

Remarks / Arguments

With this Amendment, the Applicant has amended claims 1 and 13-21, and has added claims 22-23. No new matter has been added by virtue of this Amendment. Support for this Amendment is found throughout the specification, such as at page 4, lines 19-21, and page 4, line 8.

Claims 5-6 and 11-12 were canceled in previous Amendments. Therefore, claims 1-4, 7-10, and 13-23 are currently pending in this application.

1. Claim Rejections - 35 U.S.C. §103

a. Shayan in view of Frank et al.

Claims 1-3, 7, 13-18, and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shayan in view of Frank et al. However, although the Office Action, on page 2, paragraph 3, states that claim 7 is rejected over Shayan in view of Frank et al., the Office Action later states that the rejection of claim 7 under Shayan and Frank et al. has been withdrawn. (Office Action, page 8, paragraph 1.) Therefore, the Applicant understands the claims rejected as being unpatentable over Shayan in view of Frank et al. to be claims 1-3, 13-18, and 20.

The Examiner states that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Shayan’s device with a removable hood as taught by Frank for allowing the user to better direct the vapor into the nose for inhalation.” (Office Action, page 3, paragraph 1.) However, as stated in the M.P.E.P., “[i]t is improper to combine references where the references teach away from their combination.” M.P.E.P. §2145, X.D.2. (citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983)). The Applicant respectfully asserts that it is improper to combine the references of Shayan and Frank et al., because Shayan teaches away from this combination. Specifically, Shayan teaches away from the combination of the Shayan device with the removable hood of the Frank et al. device.

Shayan describes a very controlled system for heating air and passing it over the substance to create a substance vapor air stream, which is delivered through venturi tube receptacle 40 to opening 11, without incorporating any ambient air into the vapor stream prior to

the user inhaling the vapor stream. *See* col 5, line 40 – col. 6, line 14; col. 7, lines 23-33. The careful control of the temperature of the air that passes over the substance is critical, because this control of the temperature of the air allows the Shayan device to deliver the substance vapor air stream at the correct temperature over time. *See* col. 6, lines 19-23. The correct temperature must be used in order to “release [active elements of a substance] without burning the substance and without creating the toxic byproducts of combustion and denaturing of the initial source material while effectively and optimally delivering a multitude of active elements.” Col. 2, lines 41-48. The air vents 16 in Shayan are for cooling the heater or as an exhaust for the fan, but they do not combine the substance vapor air stream with ambient air prior to the vapor being released through opening 11. *See* col. 6, lines 48-50.

In contrast, Frank et al. discloses ambient air inlet vents 136 and 147 located in the hood of the Frank et al. device, through which ambient air flows into the unit. *See* col. 7, lines 36-46; col. 7, lines 62-65. Notably, the ambient air inlet vents allow ambient air to enter the unit after the steam leaves the steam generating section 12, but before the steam is released to the user through hood 14. *See* Fig. 1. Frank et al. states that the ambient air inlets 147 serve to cool the steam prior to “impingement on the user’s face.” Col. 7, line 67.

As discussed above, careful control of the temperature of the vapor air stream is critical to the Shayan device. Because of the variations in the amount and temperature of the ambient air allowed to mix with the steam in the Frank et al. device just prior to inhalation, it is not possible to reliably control the temperature of the steam prior to its inhalation. Because the reliable control of the temperature of a vapor stream is critical to the operation of the Shayan device, Shayan teaches away from the combination of its device with the Frank et al. hood.

Moreover, there is no suggestion or motivation to modify the Shayan device by combining the device with the Frank et al. hood, because such a modification would render the Shayan device unsatisfactory for its intended purpose. *See* M.P.E.P. §2143.01, V. Specifically, this modification would render the Shayan device unsatisfactory for the purpose of using a very high degree of temperature control to produce and deliver a vapor stream to a user for inhalation. In addition, in those instances in which the Shayan device is used for supplying a particular dose or concentration of a vapor by measuring the flow rate of the vapor through the venturi tube in receptacle 40, the uncontrolled mixing of ambient air as with the hood in Frank et al. would

render the modified Shayan device unsatisfactory for its intended purpose, as the dosage would be uncontrollably and irregularly diluted just prior to the user's inhalation of the vapor stream.

Even if the combination of the Shayan and Frank et al. references were proper, such a combination would not result in the claimed invention. Shayan and Frank et al., either alone or in combination, do not teach or suggest all of the features recited in claim 1, as amended. For instance, neither Shayan nor Frank et al., alone or in combination, teaches or suggests a lid comprising "a central depressed area of a size and shape whereby during use a user's nasal area is loosely engaged by the central depressed area, and wherein the lid further comprises at least one vent, wherein each vent is smaller in area than the opening of the reservoir," as recited in the amended claim 1.

The Examiner states "Shayan does not disclose that the vapor-concentrating lid comprises a central depressed area for loosely engaging a user's nasal area." (Office Action, page 2, paragraph 4.)

The Examiner goes on to cite Frank et al. to make up for this deficiency in Shayan, stating "[d]epending on how hard the user presses his or her face into the area, the nasal area would be loosely engaged." However, as discussed above, the combination of Shayan and Frank et al. yields a device unsatisfactory for its intended purpose.

The Examiner referred to the hood section 14 as a lid. (Office Action, page 2, paragraph 4.) Frank et al. does not teach or suggest that a vent of hood section 14 is smaller in area than an opening 102 of the reservoir 12. As shown in Figs. 1 and 2, the rim or "vent" in the lid 14 through which steam is inhaled is the rim of the upper margin 140, against which a user rests his or her face during use of the Frank et al. device. *See* col. 7, lines 50-58.

The Examiner states that "although Frank does not explicitly disclose that the vents are smaller in area than the opening of the reservoir, [E]xaminer contends that is an obvious design consideration to one of ordinary skill in the art to size the vents such that they would be smaller than the opening of the reservoir (11), since such a modification would have involved a mere change in the size of a component inasmuch as the vents still allowed ambient air to flow in and out of the hood." (Office Action, page 3, paragraph 1.) However, Frank et al. teaches away from sizing the rim of the upper margin of the lid 14 such that this rim would be smaller than the openings 102 of the reservoir. Frank et al. discloses that during use of the Frank et al. device, the

user's face is "in sealing engagement with the upper margin of the hood section." Col. 3, lines 24-25. A recessed region of the upper margin of the lid is "for receiving and/or supporting a portion of the user's jaw/neck," while a second recessed region is "for closely sealing against the bridge of the user's nose." Col. 7, lines 50-56. Segments of the upper margin of the lid "extend below the eyes for sealing against the user's cheekbones." Col. 7, lines 56-58. The reason for an arrangement in which the user's face is in sealing engagement with the upper margin of the lid is that "[a]s a result of this arrangement the steam directed through the hood section 114 impinges upon the user's nose and mouth, without unduly irritating his or her eyes." Col. 7, lines 59-62. The rim or "vent" of the Frank et al. device is therefore designed so that a user can rest his or her face against it in such a way that the user's nose and mouth are located above the openings 102, with the edge of the "vent" sealing against the bridge of the user's nose and the user's cheekbones, so that the user's eyes are kept out of the path of the steam emanating from the device.

If the area of the vent was decreased in size, which, according to the Examiner, is a "mere change in size of a component," a user would not be able to rest his or her face against the vent in the same manner, thereby potentially exposing his or her eyes to the steam from the Frank et al. device. Therefore, Frank et al. teaches away from the Examiner's rationale of merely changing the size of the rim or "vent" of its device such that it would be smaller than the opening of the reservoir. Consequently, it would not have been obvious for one of ordinary skill in the art to design each vent of the lid of a vapor-generating device so that each vent would be smaller in area than the opening of the reservoir.

In sum, the combination of Shayan and Frank et al. is not proper, because Shayan teaches away from such a combination since the combination yields a device unsatisfactory for its intended purpose, and Frank et al. not only does not make up for the stated deficiencies in Shayan, but actually teaches against making the very modifications rationalized by the Examiner as being "an obvious design consideration" (Office Action, page 3, paragraph 1).

Even if the combination were proper, neither Shayan nor Frank et al., alone or in combination, teaches or suggests a lid comprising "a central depressed area of a size and shape whereby during use a user's nasal area is loosely engaged by the central depressed area, and wherein the lid further comprises at least one vent, wherein each vent is smaller in area than the

opening of the reservoir.” As noted above, Frank et al. actually teaches away from such a device. Therefore, the differences between the invention of claim 1 and the combination of Shayan and Frank et al. would not have been obvious to one of ordinary skill in the art, and the Examiner has not provided any tenable rationale to support her contention that the combination of elements would have been obvious to one of ordinary skill in the art. Consequently, the invention of claim 1, as amended, is not obvious in light of Shayan and Frank et al.

Claims 2, 3, and 18 are dependent on claim 1, and therefore are also not obvious in light of Shayan and Frank et al.

Claim 13, as amended, is not obvious in light of Shayan and Frank et al. for the same reasons that claim 1 is not obvious. Claim 20 is dependent on claim 13, and therefore is also not obvious in light of Shayan and Frank et al.

With regard to claims 14-17, the Examiner states that the “modified device disclosed by Shayan and Frank has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim.” (Office Action, page 3, paragraph 4).

The Applicant respectfully asserts that a device made from the combination of Shayan and Frank et al. would not have all of the features needed to perform the recited method steps of claims 14-17, as amended. Claims 14-17, as amended, each include the method step of “connecting a lid comprising at least one vent, wherein each vent is smaller in area than the opening of the reservoir, . . . to the reservoir.”

As discussed above with regard to claim 1, neither Shayan nor Frank et al., alone or in combination, teaches or suggests a lid comprising “a central depressed area of a size and shape whereby during use a user’s nasal area is loosely engaged by the central depressed area, and wherein the lid further comprises at least one vent, wherein each vent is smaller in area than the opening of the reservoir.” In fact, Frank et al. actually teaches away from such a device. Therefore, a device made from the combination of Shayan and Frank et al. would not include a lid comprising a central depressed area of a size and shape whereby during use a user’s nasal area is loosely engaged by the central depressed area, and wherein the lid further comprises at least one vent, wherein each vent is smaller in area than the opening of the reservoir.

Accordingly, a device made from the combination of Shayan and Frank et al. would not include all of the features necessary to perform the recited method steps of claims 14-17, and it would not have been obvious to one of ordinary skill in the art, upon seeing a device made from the combination of Shayan and Frank et al., to perform the recited method steps.

For the foregoing reasons, claims 1-3, 13-18, and 20 are not obvious in light of Shayan and Frank et al. Reconsideration of the rejection of these claims is respectfully requested.

b. Nielsen in view of Fuisz et al.

Claims 1-3, 7, 8, and 13-21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nielsen in view of Fuisz et al.

Nielsen and Fuisz et al., either alone or in combination, do not teach or suggest all of the features recited in claim 1, as amended. The amended claim 1 recites a lid “adapted to concentrate a vapor from the reservoir, and to emit said vapor through the at least one vent.” The Examiner has designated the bottom 22 of the Nielsen device as a reservoir, the upper portion 12 as a lid, and the holes 14 as vents. However, Nielsen, either alone or in combination with Fuisz et al., does not teach or suggest a device wherein vapor from the bottom 22 is concentrated by the upper portion 12 and emitted through the holes 14.

In the Nielsen device, “CO₂ gas released from dry ice pellets,” which are located in the bottom portion 20 of the device, “will bubble to the surface of the liquid and can exit from the open rim . . . of the vessel.” Col. 3, lines 8-11. When the CO₂ passes through the holes 14, the CO₂ is not a vapor concentrated by the upper portion 12; instead, the CO₂ is either a solute dissolved in the liquid in which the holes 14 are submerged, or it is in the form of bubbles rising up through the liquid. See col. 3, lines 27-30. There is no teaching or suggestion in Nielsen that dissolved CO₂ or CO₂ bubbles are concentrated by the upper portion 12.

Moreover, CO₂ vapor is emitted from the Nielsen device “as a vapor . . . rising out of the open rim (601) of the vessel.” Col. 3, lines 29-30. Therefore, the vapor emitted from the Nielsen device is emitted through the open rim 601, and not through the holes 14. Consequently, the open rim 601, rather than the holes 14, is the “vent” of the Nielsen device. There is no teaching or suggestion in Nielsen that the “vent” is “smaller in area than the opening of the reservoir,” as recited in claim 1.

Fuisz et al., cited by the Examiner as disclosing effervescent compositions immersed in water, does not compensate for these deficiencies of Nielsen.

In sum, Nielsen and Fuisz et al., either alone or in combination, do not teach or suggest a lid comprising “at least one vent, wherein each vent is smaller in area than the opening of the reservoir, and wherein the lid is adapted to concentrate a vapor from the reservoir, and to emit said vapor through the at least one vent.” Moreover, the differences between the invention of claim 1 and the combination of Nielsen and Fuisz et al. would not have been obvious to one of ordinary skill in the art, and the Examiner has not provided any tenable rationale to overcome these differences. Consequently, the invention of claim 1, as amended, is not obvious in light of Nielsen and Fuisz et al.

Claims 2, 3, 7, 8, 18, and 19 are dependent on claim 1, and therefore are also not obvious in light of Nielsen and Fuisz et al.

Claim 13, as amended, is not obvious in light of Nielsen and Fuisz et al. for the same reasons that claim 1 is not obvious. Claims 20 and 21 are dependent on claim 13, and therefore are also not obvious in light of Nielsen and Fuisz et al.

With regard to claims 14-17, the Examiner states that the “modified device disclosed by Nielsen and Fuisz et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim” (Office Action, page 5, paragraph 4).

The Applicant respectfully asserts that a device made from the combination of Nielsen and Fuisz et al. would not have all of the features needed to perform the recited method steps of claims 14-17, as amended. Claims 14-17, as amended, each recite the step of “connecting a lid comprising at least one vent, wherein each vent is smaller in area than the opening of the reservoir, . . . to the reservoir whereby an amount of humidified air forms in the reservoir, is concentrated by the lid, and is emitted through the at least one vent.” As discussed above with regard to claim 1, neither Nielsen nor Fuisz et al., alone or in combination, teaches or suggests a lid comprising “at least one vent, wherein each vent is smaller in area than the opening of the reservoir, and wherein the lid is adapted to concentrate a vapor from the reservoir, and to emit said vapor through the at least one vent.” Claims 14-17 refer to “humidified air” rather than to

“vapor”; however, it is also the case that neither Nielsen nor Fuisz et al., alone or in combination, teaches or suggests a lid adapted to concentrate humidified air from the reservoir, and to emit the humidified air through the at least one vent.

Accordingly, a device made from the combination of Nielsen and Fuisz et al. would not include all of the features necessary to perform the recited method steps of claims 14-17, and it would not have been obvious to one of ordinary skill in the art, upon seeing a device made from the combination of Nielsen and Fuisz et al., to perform the recited method steps.

For the foregoing reasons, claims 1-3, 7, 8, and 13-21 are not obvious in light of Nielsen and Fuisz et al. Reconsideration of the rejection of these claims is respectfully requested.

c. Nielsen in view of Fuisz et al. and further in view of Silten

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Nielsen in view of Fuisz et al. and further in view of Silten.

The Examiner states that it would have been obvious “to have used substances including excipients and dyes as taught by Silten in the modified device of Nielsen.” (Office Action, page 6, paragraph 1.) However, as discussed above under section 1.b., the modified device of Nielsen does not result in the invention of claim 1. Using substances taught by Silten in such a modified device does not compensate for the deficiencies of Nielsen and Fuisz et al. Claims 9 and 10 are dependent on claim 1. Therefore, using substances taught by Silten in the modified device of Nielsen does not result in the inventions of claims 9 and 10.

In addition, claim 9 recites that the “effervescent composition” of the portable vapor inhaler includes one or more components selected from a group which includes an excipient. Claim 10 recites that the “effervescent composition” of the portable vapor inhaler includes a coloring agent. The Examiner states that “Silten discloses a device for the inhalation of vapors comprising substances with excipients . . . and dyes.” (Office Action, page 6, paragraph 1.) However, Silten does not disclose a device for the inhalation of vapors comprising an “effervescent composition” including excipients and/or coloring agents. Shayan, Frank et al, and Silten, either alone or in combination, do not teach or suggest a portable vapor inhaler comprising an effervescent composition, wherein the effervescent composition includes an excipient and/or a coloring agent. Moreover, the differences between the devices of claims 9 and

10 and the combination of Shayan, Frank et al., and Silten would not have been obvious to one of ordinary skill in the art.

Consequently, claims 9 and 10 are not obvious in light of Shayan, Frank et al., and Silten. Reconsideration of the rejection of claims 9 and 10 is respectfully requested.

d. Shayan in view of Frank et al. and further in view of Ninkov

Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Shayan and Frank et al. and further in view of Ninkov.

As discussed above under section 1.a., claim 1 is not obvious in light of Shayan and Frank et al. Because claim 8 is dependent on claim 1, claim 8 is also not obvious in light of Shayan and Frank et al. Ninkov does not compensate for the deficiencies in Shayan and Frank et al. discussed above, because Ninkov fails to teach or suggest the structure of any device related to the inhalation of vapors.

Therefore, claim 8 is not obvious in light of Shayan, Frank et al., and Ninkov. Reconsideration of the rejection of claim 8 is respectfully requested.

e. Shayan in view of Frank et al. and further in view of Silten

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shayan and Frank et al. and further in view of Silten.

The Examiner states that it would have been obvious “to have used substances including excipients and dyes as taught by Silten in the modified device of Shayan and Frank.” (Office Action, page 7, paragraph 1.) However, the “modified device of Shayan and Frank” would not have been obvious to one of ordinary skill in the art because, as discussed above under section 1.a., the combination of Shayan and Frank et al. is not a proper combination of references. Silten provides no teaching that would render the combination of Shayan and Frank et al. proper.

Moreover, as discussed above under section 1.a., even if the combination of Shayan and Frank et al. were proper, the resulting device would not result in the invention of claim 1. Using substances taught by Silten in the resulting device does not compensate for the deficiencies of Shayan and Frank et al. Claims 9 and 10 are dependent on claim 1. Therefore, using substances

taught by Silten, in the device resulting from the combination of Shayan and Frank et al., does not result in the inventions of claims 9 and 10.

In addition, claim 9 recites that the “effervescent composition” of the portable vapor inhaler includes one or more components selected from a group which includes an excipient. Claim 10 recites that the “effervescent composition” of the portable vapor inhaler includes a coloring agent. The Examiner states that “Silten discloses a device for the inhalation of vapors comprising substances with excipients . . . and dyes.” (Office Action, page 7, paragraph 1.) However, Silten does not disclose a device for the inhalation of vapors comprising an “effervescent composition” including excipients and/or coloring agents. Shayan, Frank et al, and Silten, either alone or in combination, do not teach or suggest a portable vapor inhaler comprising an effervescent composition, wherein the effervescent composition includes an excipient and/or a coloring agent. Moreover, the differences between the devices of claims 9 and 10 and the combination of Shayan, Frank et al., and Silten would not have been obvious to one of ordinary skill in the art.

Consequently, claims 9 and 10 are not obvious in light of Shayan, Frank et al., and Silten. Reconsideration of the rejection of claims 9 and 10 is respectfully requested.

2. Request for Reconsideration and Allowance

Based upon the above Amendments and Remarks, claims 1-4, 7-10, and 13-23, as amended, are believed to be in proper form for allowance, and patentable over the prior art made of record. New claims 22 and 23, which are dependent on claims 1 and 13, respectively, are not obvious over the cited prior art for the same reasons that claims 1 and 13 are not obvious. Applicant respectfully requests reconsideration of the claim rejections and consideration of the new claims, and requests that a timely Notice of Allowance be issued in this case.

Please direct any questions or comments regarding this application to Audrey J. Babcock
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Respectfully submitted,
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Dated: April 28, 2008

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